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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/092,210 | 03/06/2002 | Iwao Katsuyama | KUP-D0201 | 8614 |
| 2292 | 7590 | 05/04/2005 | EXAMINER | |
| BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | SHARAREH, SHAHNAM J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,210

Applicant(s)

IWAO KATSUYAMA

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/29/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment filed on January 05, 2005 has been entered. Claims 19-27 are now pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments filed on January 05, 2005 have been fully considered but are not found persuasive, because they are not commensurate with the scope of the claims. Each argument is addressed in the appropriate section below.

Claim Rejections - 35 USC § 112

Claims 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

In claims 19-23, the omitted steps are: the actual step of inducing ciliary muscles contraction, evaluating the results, administering the medicine, correlating the results to the effects of medicine.

In claims 24-27, it is not clear what is the active step correlating the results with the effects of a medicine against asthenopia. In fact, it is not clear that is the correlation between the activity of the medicine and the results obtained. Claims 24 does not require administration of any medicine for assessment.

The term "substantially stable decrease" in claim 19 and 24 is a relative term, which renders the claim indefinite. The term "substantially stable decrease" is not defined by the claim, the specification does not provide a standard for ascertaining the

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requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It not clear what is the stable decrease of $50 \pm 30\%$ relative to?

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

With respect to the omission of steps, applicant argues that claims 19-23 are related to an experimental model for evaluating the effect of a medicine against asthenopia and that the contraction of ciliary muscles are not technically a step. (see arguments at page 5).

Frankly, Examiner is at loss in interpreting such line of arguments. Applicant's arguments appear to categorize the claimed "experimental model" as a nonstatutory subject matter. Nevertheless, Examiner believes that the claimed invention can still qualify as process claims.

During patent Examination, to properly determine whether a claimed invention complies with statutory requirement, a claimed invention is first classified into its proper statutory category. (see MPEP 2106 III B). The statutory categories are well articulated in MPEP § 2106 IV. 2). Accordingly, a claimed invention can be classified as a composition of matter, a machine, or a process. *Id.* There appears to be no dispute here as to the instant claims not being directed to a composition of matter.

To be categorized as a machine, the claim must be directed towards a concrete thing, consisting of parts or certain devices and combination of devices. See MPEP

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2106 IV B 2 (a), and also *Burr v. Duryee*, 68 US. (1 Wall.) 531, 570 (1863). The instant claims clearly lack such requirements. Thus, they were not classified as a machine.

A statutory process claim requires one or more acts to be performed. see MPEP 2106 IV B 2 (b). Accordingly, the process can be a mode of treatment of certain materials to produce a given results or an act or series of acts that requires certain things to be done with certain substances and in certain order, but the tools to be used in doing this may be of secondary consequence. *Id.* In fact, for the purposes of classifying a claim as a patentable subject matter, "it is of little relevance whether the claim is directed to machine or a process. The legal principles are the same." *AT&T Corp. v. Excel Communications, Inc.* 50 USPQ2d, 1447, 1451 (Fed. Cir 1999).

Here, the Examiner has classified the claimed "Experimental Model" as a process claim. Under 35 USC 112, 2nd para., such type of process claims require to have active steps. The instant claims lack such steps. First, when and how ciliary muscles are contracted, how such contraction is evaluated and what is the correlation with the ciliary muscle contraction and effect of a medicine. Thus, the claims do not comply with the 35 USC 112, 2nd para. If Applicant believes that the claimed "experimental model" is a machine or apparatus, then the claims must be articulated in a manner rendering different parts of such machine.

Applicant then adds, "there is no requirement for a step involving evaluation of results per se." (see arguments at page 6, 1st para). In response, Examiner states that applicant has not identified the legal basis for such conclusion. Thus, such allegations are not viewed substantive and thus not found persuasive.

Claim Rejections - 35 USC § 102

Claims 19-21, 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 07-133225 ("JP '225").

The instant claims are directed to methods for evaluating the action of a drug against ciliary muscles comprising the steps of inducing contraction of ciliary muscles and contacting ciliary muscles with a medicine and assessing the decrease in ciliary muscle tension.

JP '225 describes methods of performing a pharmacological test to assess the effects of a drug on ciliary muscle contraction for treatment of asthenopia. (abstract). Examiner points out in the process claims, the intended use does not impart patentability over the prior art absent a manipulative difference. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). The methods of JP '225 meet all elemental steps of the instant claims.

The method in JP '225 comprise extracting the ciliary muscles of a cow eyeball which meets the instant step of enucleating ciliary muscles of a non-human mammal. (see para 0022-0023). The method of JP '225 also comprises hanging the ciliary muscle and placing it in a Magnus apparatus (tubing) and applying a compound of interest (compound A) to the hung muscle and then determining the contraction strength of the ciliary muscles. (see para 0023). Thus, all process steps of the instant claims are met. The ciliary muscles in JP '225 are first contracted or pretreated with compound A to induce asthenopia. This step in JP '225 meets the limitation of inducing contraction of

ciliary muscles. Even, the step of adding KCl in JP '225 meets the instant step of contacting a "medicine" to the contracted muscles. JP '225 describes that the rate of decrease in tension was about 22.9% which meets the limitations of the instant claims. Accordingly, JP '225 anticipates all method steps of the instant claims.

Applicant's arguments with respect to this prior art have been fully considered but are not persuasive. Applicant argues that JP pretreats ciliary muscles with KCl after treatment with a medicine. (see page 7, 2nd para.).

In response, Examiner states that such line of argument are not commensurate with the scope of the pending claims. During patent examination, the claims are viewed given their broadest reasonable interpretation consistent with the specification. Here, the instant claims do not exclude the method steps of JP '225. In fact, the recitation of instant medicine does not exclude the use of KCl or the Compound A of JP '225 in any specific order. Second, the instant open-ended transitional phrase does not require any specific sequence of employing an inducing agent or a medicine for ascertaining the therapeutic benefit of the medicine under investigation.

Applicant also argues that the state of asthenopia in the instant claims are caused by repeatedly contracting the ciliary muscles in vitro with an inducer of smooth muscle contraction. (see Arguments at page 7, 2nd para.). In response, Examiner states again that applicant is arguing unclaimed limitation. Further, the KCl of JP '0225 meets the limitation allegedly argued by Applicant. Thus, Applicant's arguments are not found persuasive.

Claim Rejections - 35 USC § 103

Claims 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '225 in view of Kitagaw (Japanese Journal of Pharmacology, 1989, Vol 49, suppl. Pp. 281 and Yoshikawa US Patent 5,338,668.

JP '225 are described above. JP '225 only fails to specifically recite various types of stimulants, chemical or electrical, that may be used for contracting the ciliary muscles recited in instant claim 22.

Kitagaw teaches acetylcholine-induced contraction of smooth muscles and measuring the degree of contraction by automated and manual Magnus apparatus.

Yashikawa teaches the state of art in assessing the effects of drugs on smooth muscles before and after the electrical stimulation of the muscle. Yashikawa employs such method for measuring the degree of muscle contraction after it has been treated with a drug of choice (see col 12, lines 53-col 13, lien 8).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to assess the activity of Compound A in JP '225 against other chemical stimulants such as acetylcholine, as described by Kitagaw, or direct electrical stimulation, as described by Yoshikawa.

One of ordinary skill in the art would have had a reasonable expectation of success in achieving meaningful clinical data by predicting the degree of contraction of ciliary muscles against other known stimulants. Further, assessing the degree of contraction decrease is a function of the doses of an agonist or antagonist drug employed and is achieved by routine experimentation.

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, all limitations of the claims are described by combined teachings of the references. Accordingly, the rejection is proper for the reasons set forth above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

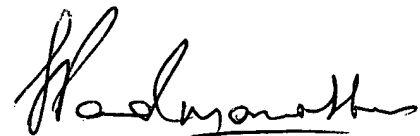
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**SREENI PADMANABHAN
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